

ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS

The following additional Technical Proposal instructions reflect the requirements of the Request for Proposals (RFP) and are meant to provide additional instructions as well as a uniform format for technical proposals. The information requested in these instructions should be used as a guide for formatting and preparing the proposal. Offerors are advised to give careful consideration to the Statement of Work (SOW), all reference material, and attachments, the technical evaluation criteria, and the RFP as a whole, in the development of their Technical Proposal.

Offerors who propose subcontracts to perform portions of the Statement of Work should clearly identify the specific sections for which they plan to utilize subcontractors, as well as the method and level of integration between the prime and subcontractor(s), and the expected advantages of such an approach.

The Government encourages the offerors to be complete but succinct in the presentation and are required to limit the total number of pages for the entire proposal to **100 pages**. Pages in excess of the page limitation will be removed from the proposal and will not be considered or evaluated.

TOTAL PAGE COUNT DOES INCLUDE: Principal Investigator's (PI's) resume/*Curriculum Vitae* (CV), with highlights of any items that are directly related to the subject project, indicated by preceding them with a double asterisk (**).

TOTAL PAGE COUNT DOES NOT INCLUDE (some of which may be added as appendices): Title and Back Page; NIH-2043; Table of Contents; Section Dividers that do not contain information other than title of Section; Resumes/CVs of other key personnel (same information and format as used for the PI); certificates and licensures, Standard Operating Procedures (SOP), letters of commitment by proposed consultants and subcontractors.

FORMATTING AND LAYOUT:

Use your usual word processing and spreadsheet programs to prepare and format the technical and business proposals.

Documents submitted using Adobe .pdf shall be submitted using a .pdf searchable format.

- Type size must be 10 to 12 points.
- Type spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
- Print margins must be at least one inch on each edge of the paper.
- Print setup should be single-sided on standard letter size paper (8.5 x 11").
- Offerors shall **NOT** use 8.5 x 14 legal size paper.
- Proposals shall **NOT** include links to Internet Web site addresses (URLs) or otherwise direct readers/reviewers to alternate sources of information.
- Additional appendices may be added as needed.
- The proposal with pagination, including appendices, shall be formatted sections, cross referenced, and include a detailed Table of Contents with page references.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

General Instructions

SECTION 1

- A. PROPOSAL TITLE PAGE.** Include RFP title and number, name of organization, DUNS number, proposal part, and identify if the proposal is an original or a copy.
- B. PROJECT OBJECTIVES** (NIH FORM 1688-1)
- C. GOVERNMENT NOTICE FOR HANDLING PROPOSALS**
- D. PROPOSAL SUMMARY AND DATA RECORD** (NIH-2043)
- E. TABLE OF CONTENTS**

Section L of the RFP specifies the minimum documentation requirements for cost data and all cost related support. All related documentation should be included in the proposal in a clearly marked section. Cost and Pricing support should be provided for all proposed subcontractors.

SECTION 2 TECHNICAL DISCUSSIONS

A. Personnel and Experience

General:

Describe the experience, qualifications and availability of all personnel who will be assigned for direct work on this project. Information is required which shows the composition of the task or work group, its general qualifications and recent experience with similar programs. Each area of the Statement of Work shall be addressed in sufficient detail to permit evaluation of the proposal in terms of the adequacy and availability, as needed, of all staff to be assigned to the project. Indicate the approximate percentage of total time each could be made available for this contract and specifically to which tasks each employee would be assigned. Within the total level of effort offerors should indicate the specific level of effort which they consider appropriate for each function outlined in the Statement of Work. Provide a Personnel Ranking Matrix which indicates the hierarchical line of supervisory authority, and indicate which contractor employee(s) will perform the various tasks. State the estimated time to be spent on the project.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

Provide complete detailed resumes of the Project Manager and other specialists. Resumes should include educational background and related experience. In particular, experience with clinical trials or biomedical environment should be included. Include dates, places and names of previous employers, and any related training.

1. Program Manager:

In general, it is expected that the Program Manager shall possess relevant education and/or at least three years of management experience in the health care/clinical research fields. The CV of the individual should include all relevant education and any certifications earned. As the Program Manager shall be responsible for coordinating all Contractor activities pertaining to the work specified in the Statement of Work (SOW), this individual should demonstrate self-motivation, superior project and personnel management, effective communication, organization and process improvement skills. Specifically, he/she should demonstrate knowledge and experience in clinical trials development processes (both scientific and administrative); and knowledge and experience within the oncology community. He/she should possess overall management capabilities, which would permit the effective implementation of all tasks on the project, including demonstrated experience in supervising all efforts of the type to be conducted under the contract, including managing teams of health care professionals at all levels. He/she should possess knowledge and experience with business improvement practices, which includes knowledge of quality control and quality assurance methods for all contract activities. He/she should demonstrate their experience in dealing with health care professionals at all levels, including effective use of both verbal and written communication skills and ability to provide successful presentations to those professionals, including orientation of new staff members. He/she should demonstrate experience with utilization of databases (including data element abstraction, milestone entry, generating queries and running canned reports), document management systems, the Internet and Microsoft Office software products, including experience with word processing and spreadsheet software. He/she should demonstrate their education and knowledge of medical terminology. He/she should demonstrate their knowledge and experience with the development and administration of survey tools.

2. Deputy Program Manager:

In general, it is expected that the Deputy Program Manager shall possess relevant education and/or management experience in the health care/clinical research fields. The CV of the individual should include all relevant education and any certifications earned. As the Deputy Program Manager shall be responsible for assisting the Program Manager--and serving in the Program Manager's capacity during the Program Manager's absence--in the coordination of all Contractor activities pertaining to the work specified in the Statement of Work (SOW), this individual should demonstrate self-motivation, superior project and personnel management, effective communication, organization and process improvement skills. Specifically, he/she should demonstrate knowledge and experience in clinical trials development processes (both scientific and administrative aspects); and knowledge and experience within the oncology community. He/she should possess overall management capabilities, which would permit the effective implementation of all tasks on the project, including demonstrated experience in supervising all efforts of the type to be conducted under the contract, including managing teams of health care professionals at all levels. He/she should possess knowledge and experience with business improvement practices, which includes knowledge of quality control and quality assurance methods for all contract activities. He/she should demonstrate their experience in dealing with health care professionals at all levels, including effective use of both verbal and written communication skills and ability to provide successful presentations to those professionals, including orientation of new staff members. He/she should demonstrate experience with utilization of databases (including data element abstraction, milestone entry, generating queries and running canned reports), document management systems, the

Internet and Microsoft Office software products, including experience with word processing and spreadsheet software. He/she should demonstrate their education and knowledge of medical terminology. He/she should demonstrate their knowledge and experience with the development and administration of survey tools.

3. Document Specialists:

List the names of all Document Specialists who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

In general, it is expected that the Document Specialists shall possess relevant education and/or experience in the health care/clinical research fields. The CV of these individuals should include all relevant education and any certifications earned. As the Document Specialists shall be responsible for performing the activities pertaining to the work specified in the Statement of Work (SOW), these individuals should demonstrate self-motivation, effective communication, organization and process improvement skills. Specifically, they should demonstrate knowledge and experience in clinical trials development processes (both scientific and administrative aspects); and their education and knowledge of medical terminology. They should demonstrate their experience with utilization of databases, including data element abstraction, milestone entry, generation of queries and running of canned reports. In addition, they should demonstrate effective use of the Internet and Microsoft Office software products, including experience with word processing and spreadsheet software. They should demonstrate their experience in dealing with health care professionals at all levels, including effective use of both verbal and written communication skills and ability to assist in providing successful presentations to those professionals, including orientation of new staff members.

4. The offeror shall maintain a backup personnel system for key personnel and key positions. Provide a detailed description of how the contract performance will be maintained during fluctuations in the personnel needs as a result of high or low levels of work, etc. Also explain in detail the plan for maintaining performance during periods of extended absences by personnel (defined as greater than 10 consecutive working days). For personnel proposed as “backup” personnel to key positions, curriculum vitae or resumes should be provided. Backups named must be thoroughly familiar with the position that they are supporting.
5. The offeror shall discuss potential problems and propose solutions.
6. Combined Range of Experience:
The technical evaluation panel will evaluate the breadth and depth of the composite experience of the offeror’s proposed team members with the tasks required by the Statement of Work to meet the protocol development needs of CTEP.
7. Demonstrated Experience of Proposed Staff:
The technical evaluation panel will evaluate the offeror’s demonstrated experience of proposed staff working together as a team. Evidence of a stable workforce and the ability to recruit and retain staff will be considered.

B. Adequacy of Technical Approach and Understanding of the Project

The proposal should include: 1) a statement of the overall objectives of the project, as envisaged by the offeror; and 2) an outline of the technical approach that would be used to achieve the objectives.

Proposals should address each area of the Statement of Work in a manner that describes the offeror's approach to the particular task and methods of quality control for the various tasks outlined in the Statement of Work. The offeror should demonstrate a clear understanding of the needs of the program and an understanding of the potential problems involved with these types of projects.

Specifically, the offeror should discuss its:

1. Approach

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed and methods of quality assurance, in achieving the project objectives. The offeror should demonstrate a clear understanding of the potential problems involved with these types of projects. Proposals which merely restate the requirements of the Government's scope of work will not be eligible for award.

Specifically, the offeror should discuss its technical understanding of the requirements of the project, which includes: an understanding of the oncology community and cancer clinical research; an explanation of the methods and approach for accomplishing the tasks outlined in the Statement of Work, in a secure, flexible and user-friendly environment. The offeror should demonstrate their ability to meet with CTEP personnel on short or little notice. The offeror should discuss its plan for start-up of work under this contract. The offeror should discuss its understanding of Quality Assurance (QA) methods, goals and objectives. Specific descriptions of how the work performed will meet or exceed the Quality Assurance goals shall be addressed. Demonstration of approach to development of a QA plan, evaluation of activities covered in the QA plan, and methods used to update the QA plan, in accordance with the indicators measured in the QASP, shall be addressed. The offeror should discuss the plan to optimize data quality and timeliness of projects and tasks, as detailed in the Statement of Work. The offeror should discuss the ability to provide daily contact with CTEP staff, by the Program Manager, Deputy Program Manager and all other contract staff, as needed, to discuss and advise on the administrative and operational aspects of the protocol development process as it impacts CTEP operations and data abstraction processes. The offeror should discuss experience with and ability to provide best business practices, regarding process improvement, continuous quality improvement principle and change management practices. The offeror should submit an example of three new QASP measures that show their understanding of PIO tasks and importance to the CTEP

Program goals. The offeror should discuss its management plan which will provide the Project Officer with up-to-date financial information, project/subproject status and staffing information. The offeror should discuss its plan for providing annual training programs (including orientation of new personnel) to CTEP personnel, CTEP contractors or submitters and submitter personnel who interact with CTEP. The offeror should discuss its transition plan that would support a smooth transfer of responsibility for the project to a new Contractor upon completion of the contract.

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

2. **Methods**

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

3. **Schedule**

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

4. **Provide a detailed description of how the Contract performance will be maintained during fluctuations in the personnel needs as a result of high or low levels of requests, etc. Also explain in detail the plan for maintaining performance during periods of extended absences by personnel. For personnel proposed as "backup" personnel to key positions, Curriculum Vitae or resumes should be provided.**

5. **Provide a communications plan on how the offeror plans to effectively communicate with the offeror's team, customer, stakeholders, and other CTEP-ESYS community. Specifically, how the contractor will be able to meet with CTEP/DCTD personnel within two hour's notice at either NCI or contractor meeting location or by use of available technologies (teleconference, webex).**

C. Organizational Experience

Offerors shall describe in detail prior experience of the organization in furnishing services similar to each area described in the Statement of work. The proposal should include sufficient information to demonstrate the previous effectiveness of the firm in similar or related work. Include documentation with specific reference to applicable contract numbers, dates of agreements and dollar volume. This documentation should include clear and concise descriptions of these projects and should indicate project sponsors (e.g., government contract or grant, etc.). Please note that organizational experience is defined as accomplishment of work, either past or ongoing that is comparable or related to the effort required by this RFP. Organization experience

should also specify the size and scope of the project referenced and if the offerer served as the prime or subcontractor. This includes overall offeror or corporate experience, but not the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in the RFP. Offerors should demonstrate experience with clinical trials including but not limited to scientific development activities, informatics supporting development processes, regulatory support efforts, and administrative/operations efforts.

The relationship of the proposed working group within the offeror's organizational structure should be described as well as how this relationship may facilitate performance on this project. Information should be provided on how staff training needs will be met. Additionally, the offeror should explain how the corporate office and expertise will provide support to this project and to the proposed Project Manager. The offeror should explain how the organization will support the project manager in resolving problems or special situations. The offeror shall demonstrate the availability of personnel proposed on the project.

D. Transition In

The offeror shall provide a plan for a transition in phase-in plan that would support a smooth transfer of responsibility from the incumbent contractor. It is anticipated that the new awardee will work with the incumbent contractor for one month during the transition in phase.